
From: Charles Boyd <CharlesB@Safechain.com>
Sent: Fri 8/21/2020 6:04:53 PM (UTC)
To: Quality Complaints <QualityComplaints@gilead.com>, Abbie Divilio <AbbieD@Safechain.com>
Cc: compliance <compliance@Safechain.com>
Subject: RE: Gilead (PR-196084)

Hi Clifford,

We are still waiting on all of the details surrounding the complaint to better understand what happened. Here is what we know as of now:

We received a complaint from our customer White Cross Pharmacy – Brawley, located in San Bernardino, CA regarding one sealed bottle of Biktarvy (NDC# 61958-2501-01). We are one of their 3 primary wholesalers who provides this product to them. We were notified by them on Monday that one bottle had supposedly been dispensed to a patient who discovered generic Excedrin in the bottle not Biktarvy. White Cross is still researching on their end as to confirm which wholesaler delivered that product. The PIC at White Cross has filed a complaint with Gilead and shipped the product back to you. This is a different Lot# than what we asked you to verify and a picture of this bottle is provided below. After doing some additional due diligence on our end we discovered that we have distributed 44 bottles of this same Lot# to roughly 20 other pharmacies. None of these other customers have had an issue that we know of.

Safe Chain only receives and ships finished products as we are only licensed as a wholesale distributor not repacker. I am not certain how something like this could happen but am 100% certain it wasn't caused by any Safe Chain policies or procedures. We assume you have reported this and are conducting an investigation. Safe Chain is more than happy to assist in any way possible and provide any additional information you may need. Please let us know how we can help or if you would like to setup a time to discuss further. Thanks and have a great weekend!

Best regards,
Charlie Boyd



Charlie Boyd | Founder & CEO
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 | Cell: 301.875.1581
www.SafeChain.com | [LinkedIn](#)

From: Quality Complaints <QualityComplaints@gilead.com>

Sent: Thursday, August 20, 2020 5:44 PM

To: Charles Boyd <CharlesB@Safechain.com>; Abbie Divilio <AbbieD@Safechain.com>

Cc: compliance <compliance@Safechain.com>; Quality Complaints <QualityComplaints@gilead.com>

Subject: RE: Gilead (PR-196084)

Hello Charlie,

Can you please clarify what was the customer complaint? Was there a product quality complaint or issue with the product?

Thank you,

Clifford Won

QA Specialist I, Commercial QA

Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404

Office: 1-800-445-3235 option 2 | Email: QualityComplaints@gilead.com



From: Charles Boyd <CharlesB@Safechain.com>

Sent: Thursday, August 20, 2020 12:54 PM

To: Quality Complaints <QualityComplaints@gilead.com>; Abbie Divilio <AbbieD@Safechain.com>

Cc: compliance <compliance@Safechain.com>

Subject: [EXTERNAL] RE: Gilead (PR-196084)

Hi Clifford,

Thank you so much for verifying this information. We had a customer complaint so we wanted to do our due diligence. Thanks again for your help!

Sincerely,

Charlie



Charlie Boyd | Founder & CEO
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 | Cell: 301.875.1581
www.SafeChain.com | [Linked in](#)

From: Quality Complaints <QualityComplaints@gilead.com>

Sent: Wednesday, August 19, 2020 1:37 PM

To: Abbie Divilio <AbbieD@Safechain.com>

Cc: compliance <compliance@Safechain.com>; Charles Boyd <CharlesB@Safechain.com>; Quality Complaints <QualityComplaints@gilead.com>

Subject: RE: Gilead (PR-196084)

Hello Abbie,

Our investigation team was able to confirm that the lot number (CCPDPA) and serial number (100008932529) are authentic Gilead product identifiers. Please let us know if you have any questions.

Kind regards,

Clifford Won

QA Specialist I, Commercial QA

Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404

Office: 1-800-445-3235 option 2 | Email: QualityComplaints@gilead.com



From: Abbie Divilio <AbbieD@Safechain.com>

Sent: Tuesday, August 18, 2020 10:58 AM

To: Quality Complaints <QualityComplaints@gilead.com>

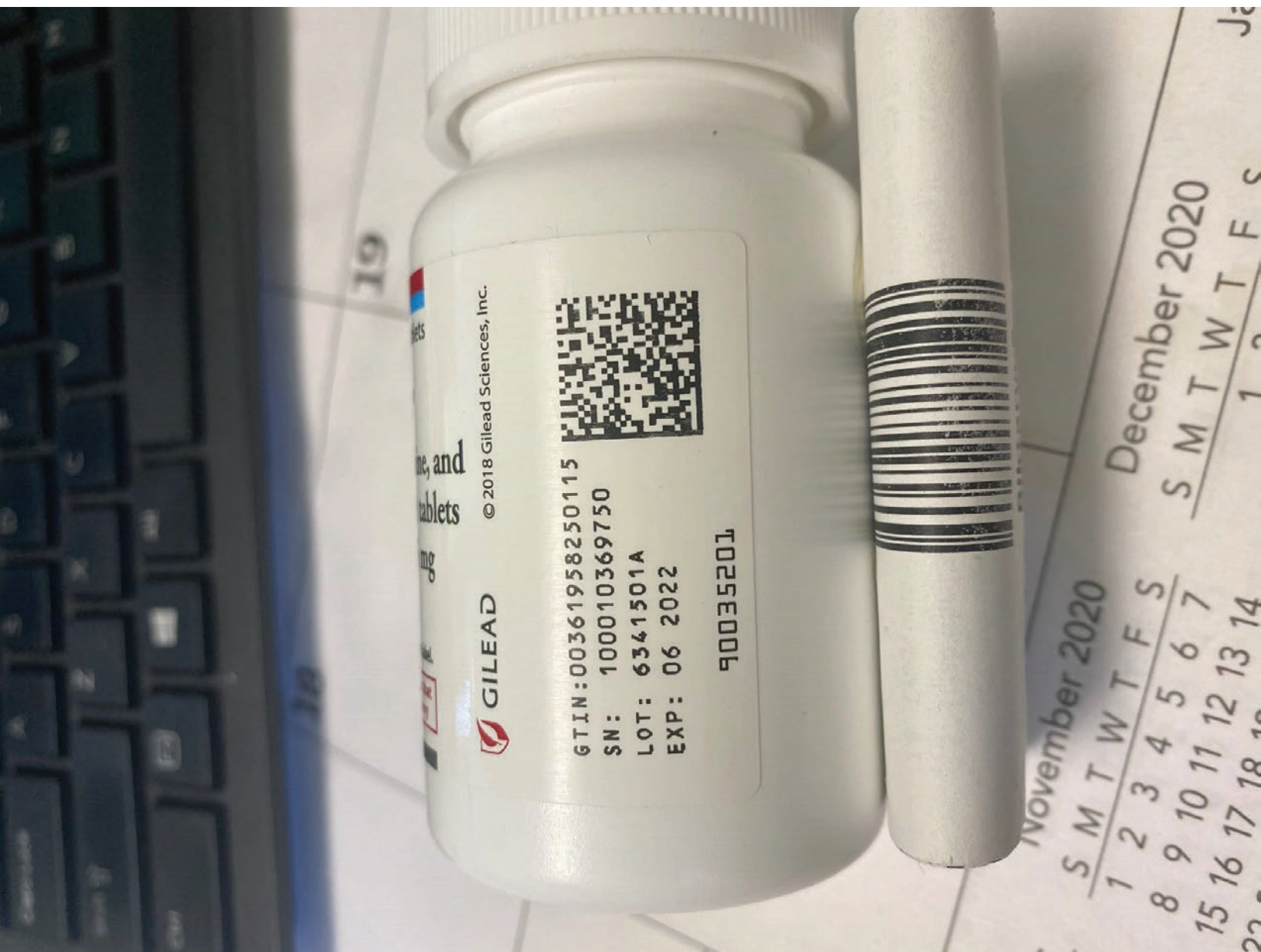
Cc: compliance <compliance@Safechain.com>; Charles Boyd <CharlesB@Safechain.com>

Subject: [EXTERNAL] RE: Gilead (PR-196084)

Hello Clifford,

I believe this may have been a bit of packing tape, or an auxiliary label from the pharmacy. I have attached another picture of another bottle in stock and it appears that the label is similar, minus the sticky patch. This picture is just an example and we do not need this verified.

Thanks,
Abbie





Abbie Divilio | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
www.SafeChain.com | [LinkedIn](#)

From: Quality Complaints <QualityComplaints@gilead.com>
Sent: Tuesday, August 18, 2020 1:27 PM
To: Abbie Divilio <AbbieD@Safechain.com>
Cc: compliance <compliance@Safechain.com>; Quality Complaints <QualityComplaints@gilead.com>
Subject: RE: Gilead (PR-196084)

Hi Abbie,

Thanks for your reply. Our investigation team will be able to confirm the lot/serial number. Can you please confirm what was placed over the Gilead label? It appears that one of the digits in the label part number (90148101) was peeled off.

Kind regards,

Clifford Won

QA Specialist I, Commercial QA
Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404
Office: 1-800-445-3235 option 2 | Email: QualityComplaints@gilead.com



From: Abbie Divilio <AbbieD@Safechain.com>
Sent: Tuesday, August 18, 2020 5:40 AM
To: Quality Complaints <QualityComplaints@gilead.com>
Cc: compliance <compliance@Safechain.com>
Subject: [EXTERNAL] RE: Gilead (PR-196084)

Good morning Clifford,

At this time, that is the only picture I have. Are you able to confirm the lot/serial number with this? I will pass on any additional pictures when I receive them.

Thank you,



Abbie Divilio | Director of Compliance
Safe Chain Solutions, LLC
822 Chesapeake Drive | Cambridge, MD 21613
office: 855.437.5727 x1017 | fax: 866.930.1128
www.SafeChain.com | [LinkedIn](#)

From: Quality Complaints <QualityComplaints@gilead.com>
Sent: Monday, August 17, 2020 6:29 PM
To: Abbie Divilio <AbbieD@Safechain.com>
Cc: compliance <compliance@Safechain.com>; Quality Complaints <QualityComplaints@gilead.com>

Subject: RE: Gilead (PR-196084)

Hi Abbie,

Would you be able to provide the additional requested photographs of the BIKTARVY bottle? This will help us to expedite your inquiry.

Thank you,

Clifford Won

QA Specialist I, Commercial QA

Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404

Office: 1-800-445-3235 option 2 | Email: QualityComplaints@gilead.com



From: Quality Complaints

Sent: Monday, August 17, 2020 11:32 AM

To: Abbie Divilio <AbbieD@Safechain.com>

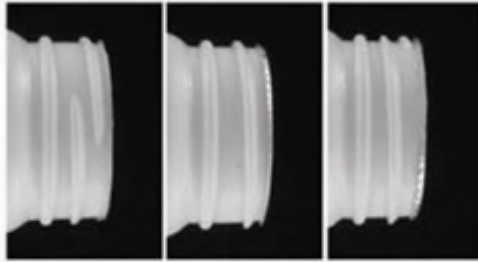
Cc: compliance <compliance@Safechain.com>; Quality Complaints <QualityComplaints@gilead.com>

Subject: RE: Gilead (PR-196084)

Hello Abbie,

Thank you for providing the photograph of the variable print area of the BIKTARVY bottle. We have assigned **PR-196084** for your inquiry.

Can you please provide additional photographs of the bottle? We would like the photographs to show the full Gilead label on the bottle, top of the cap/lid, base/underneath the bottle, inside the cap/lid, and inside the bottle. Please use the Complaint Sample Photo Template below as a guide.



Kind regards,

Clifford Won

QA Specialist I, Commercial QA

Gilead Sciences, Inc. | 333 Lakeside Drive | Foster City, CA 94404

Office: 1-800-445-3235 option 2 | Email: QualityComplaints@gilead.com



From: Abbie Divilio <AbbieD@Safechain.com>

Sent: Monday, August 17, 2020 11:21 AM

To: Quality Complaints <QualityComplaints@gilead.com>

Cc: compliance <compliance@Safechain.com>

Subject: [EXTERNAL] FW: Gilead

Good afternoon,

I am following up after having a conversation with Clifford regarding verification of this serial and lot number for Biktarvy. Please see the picture below.

I can be reached at the contact information below if necessary.

Kind regards,



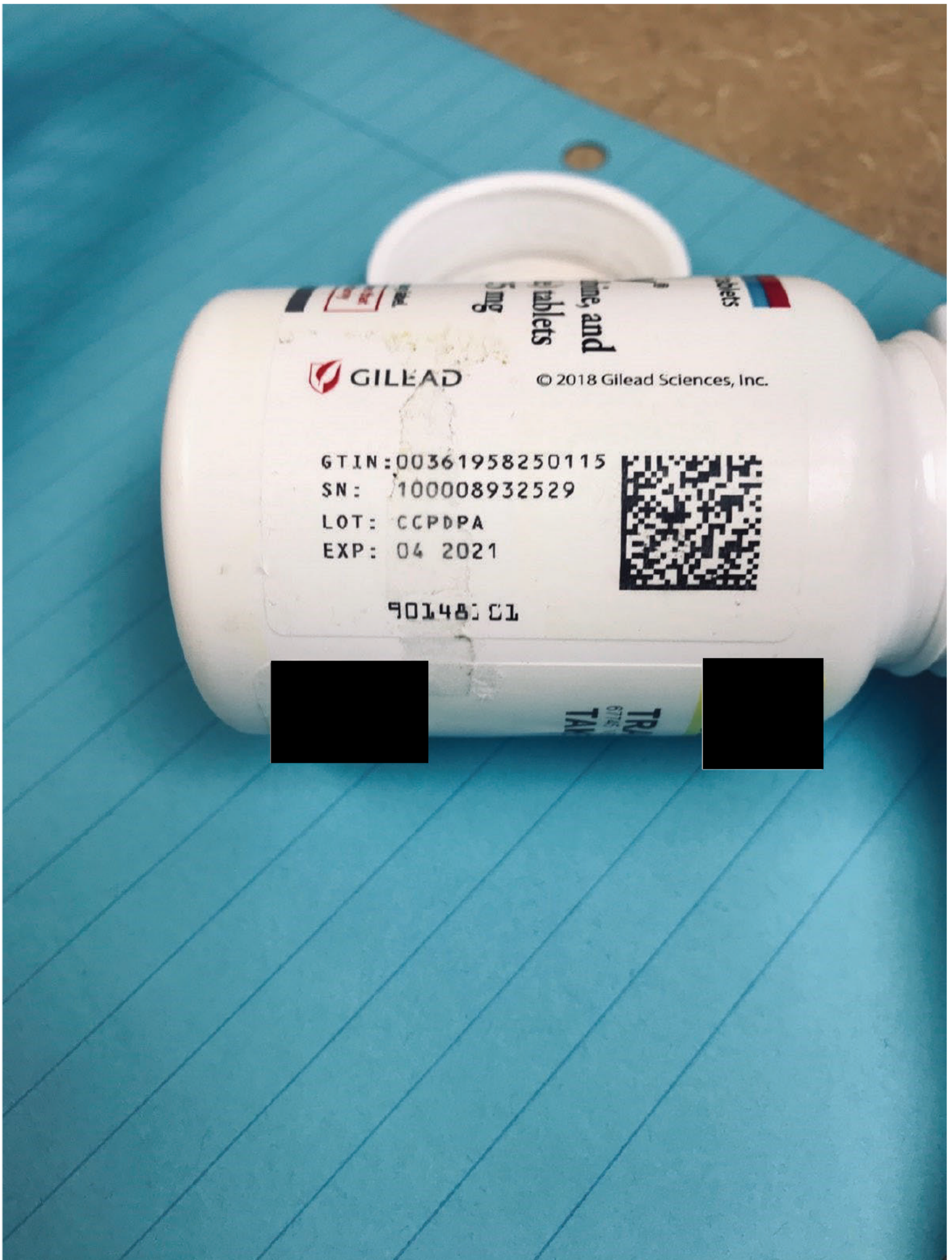
Abbie Divilio | Director of Compliance

Safe Chain Solutions, LLC

822 Chesapeake Drive | Cambridge, MD 21613

office: 855.437.5727 x1017 | fax: 866.930.1128

www.SafeChain.com | [LinkedIn](#)



GILEAD

© 2018 Gilead Sciences, Inc.

GTIN: 00361958250115

SN: 100008932529

LOT: CCPDPA

EXP: 04 2021



90148101